# RAPINDO™

## HIV Screen

**Rapid test for simultaneous / differential detection of total antibodies to HIV 1 & HIV 2 in human serum / plasma**

DEVICE

### INTENDED USE

**RAPINDO™ HIV Screen**, is a rapid, 3rd generation, qualitative, sandwich immunoassay for simultaneous and differential detection of total antibodies i.e. IgG, IgM, IgA etc to HIV-1 and HIV-2 virus in human serum / plasma. For Professional use.

### SUMMARY

Acquired immuno deficiency syndrome (AIDS) is caused by at least two retroviruses, the HIV 1 and the HIV 2, collectively referred to as HIV 1 /2. Antibodies to HIV 1 core protein p24, transmembrane protein (gp 41) and/or antibodies to HIV 2 transmembrane protein (gp 36) are prevalent in the sera of individuals with AIDS, ARC or at high risk of contracting AIDS. Detection of these antibodies indicates exposure to the HIV 1/2 virus.

### PRINCIPLE

**RAPINDO™ HIV Screen** utilizes the principle of Immunochromatography, a unique two-site immunoassay on a nitrocellulose membrane. Highly purified antigens - gp41, gp120 and p24-O fusion polypeptide, representing HIV-1 and HIV-1 group "O" and synthetic peptide gp36 representing HIV-2 are stripped on the membrane as two separate test bands. An assay control forms the third band. Similar antigens are also coated on colloidal gold. A unique combination of synthetic peptides and recombinant antigens reduces cross-reactivity and enable better discrimination between HIV-1 & HIV-2 samples. As the test specimen flows through the membrane test assembly, the highly specific HIV-1/2 antigens-colloidal gold conjugate complexes with the HIV-1/2 specific antibodies in the specimen and travels on the membrane due to capillary action alongwith the rabbit IgG-colloidal gold conjugate. This complex moves further on the membrane to the test region where it is immobilized by the HIV-1/2 antigens coated on the membrane at two separate test regions for HIV-1 & HIV-2. This leads to the formation of colored band(s). The presence of colored band(s) in the test regions indicates the presence of antibodies to HIV-1/2 in the specimen.

The unreacted conjugate and unbound complex, if any, along with rabbit IgG gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit IgG antibodies coated on the membrane at the control region "C", forming a colored band. This control band acts as a procedural control and serves to validate the results.

### COMPONENT INSIDE THE KIT

**RAPINDO™ HIV Screen** kit has the following components:

A. Individual pouched devices each comprising of:
   1. DEVICE Membrane test assembly : Stripped with HIV-1 and HIV-2 specific antigens and goat anti-rabbit IgG along with HIV specific antigen and rabbit IgG gold conjugate.
   2. PIPETTE Disposable Plastic Sample Applicator.
   3. Desiccant Pouch.

B. BUF Sample Running Buffer in a dropper bottle: Buffer containing surfactant and preservatives.

C. Package insert.

### STORAGE AND STABILITY

**RAPINDO™ HIV Screen** Each test device is individually packaged in a sealed pouch and should be stored at 4–30°C. The test device must be used immediately after opening. The shelf life of the test device in the sealed pouch is 24 months.The Sample Running Buffer should be stored at a temperature between 4°C - 30°C. Sample Running Buffer has shelf life until 24 months from the date the vial is first opened. DO NOT FREEZE THIS PRODUCT.

### MATERIAL REQUIRED BUT NOT PROVIDED

1. Disinfectant
2. Disposable gloves
3. Biohazard waste container

### SAMPLE COLLECTION

1. **RAPINDO™ HIV Screen** uses human serum / plasma as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Preferably use fresh sample. However, specimen may be stored refrigerated (2-8°C) for short duration. For long storage, freeze at -20°C or below.

4. If serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
5. Repeated freezing and thawing of the specimen should be avoided.
6. Do not heat inactivate before use.
7. Do not use turbid, lipaemic and hemolysed serum/plasma.
8. Do not use hemolysed, clotted or contaminated specimens.
9. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
10. Refrigerated specimens must be brought to room temperature prior to testing.

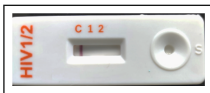
**PRECAUTIONS**

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Bring all reagents and specimen to room temperature before use.
3. Do not use beyond expiration date.
4. Read the instructions carefully before performing the test.
5. Handle all specimens as if potentially infectious.
6. Do not pipette any material by mouth.
7. Do not eat, drink or smoke in the area where testing is done.
8. Use protective clothing and wear gloves when handling samples.
9. Use absorbent sheet to cover the working area.
10. Immediately clean up any spills with sodium hypochlorite.
11. Dispose off all the reagents and material used as if they contain infectious agent.
12. Do not mix components of one lot with another.
13. If desiccant color at the point of opening the pouch has turned from blue to white, another test assembly must be run.

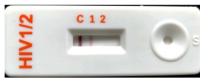
**TEST PROCEDURE**

1. Bring the sealed aluminium foil pouch of **RAPINDO™ HIV Screen** membrane test assembly to room temperature.
2. Open the pouch, take out the test device and the silica gel. Check the color of the silica gel - it should be blue. If it has turned colorless or pink, the test device should not be used. Use a device with another pouch. Once opened, the test device should be used immediately.
3. Label the membrane test assembly with specimen identity.
4. Place the membrane test assembly on a flat horizontal surface.
5. Carefully dispense **one drop (25 µl)** of serum / plasma into the specimen well "S" using the sample dropper provided.
6. Add **three drops** of sample running buffer into the same well "S".
7. Observe the development of visible colored band at Test regions ("1" for HIV-1 and/or "2" for HIV-2).
8. Positive result may be observed within 20 minutes.
9. The test should be considered invalid if the control band "C" does not appear. The test is also invalid if neither the control nor the test bands appear. Repeat the test with a new **RAPINDO™ HIV Screen** membrane test assembly.

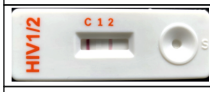
**INTERPRETATION OF RESULTS**



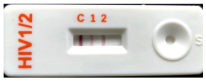

**NEGATIVE**
A colored band appears only in the control area marked "C".



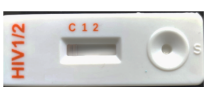

**HIV-1 POSITIVE**
A colored band appears in the control area as well as in the area marked "1". The sample is reactive for HIV-1.




**HIV-2 POSITIVE**
A colored band appears in the control area as well as in the area marked "2". The sample is reactive for HIV-2.




**HIV-1 & HIV-2 DUAL POSITIVE**
A colored band appears in the control area as well as in the areas marked "1" & "2". This indicates a mixed infection.




**INVALID**
The test should be considered invalid if the control band "C" does not appear.The test is also invalid if only the test band and no control band appear. Repeat the test with a new **RAPINDO™ HIV Screen** device.

**PERFORMANCE CHARACTERISTICS**

**External Evaluation**

**RAPINDO™ HIV Screen** was evaluated using a panel of 100 samples - 25 Reactive samples & 75 non reactive samples, in 3 different lots compare with plasma panel (ECLIA) in The Center for Biomedical and Health Genomics - Ministry of Health of Republic of Indonesia . The results of the evaluation are as follows:

| Rapindo HIV Screen | Panel Plasma (ECLIA) | | Spesivity | Sensitivity |
|---|---|---|---|---|
| | Reactive | Non Reactive | | |
| Reactive | 75 | 0 | 100% | 100% |
| Non reactive | 0 | 225 | 100% | 100% |
| Total | 75 | 225 | | |

Based on this evaluation:
Sensitivity of **RAPINDO™ HIV Screen**: 100%
Specificity of **RAPINDO™ HIV Screen**: 100%

**LIMITATIONS**

(1) **RAPINDO™ HIV Screen** alone cannot be used to diagnose HIV infection even if the sample is repeatedl reactive or has high intensity of bands.
(2) A negative result with **RAPINDO™ HIV Screen** does not preclude the possibility of exposure to or infection with HIV.
(3) Presence of a band at the test region(s) even if low in intensity or formation is a positive result.
(4) The deliberate slow reaction kinetics of **RAPINDO™ HIV Screen** is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
(5) Most positive results develop within 20 minutes. However, certain sera sample may take a longer time to flow. Therefore, negatives should be confirmed only at 30 minutes. Do not read results after 30 minutes.
(6) Since HIV-1 and HIV-2 viruses are similar in genomic structure and morphology, antibodies to them may cross react. Reactive test bands for both HIV-1 and HIV-2 do not necessarily imply mixed infection. However, to reduce cross-reactivity & better discrimination, **RAPINDO™ HIV Screen** uses a synthetic peptide gp36 with highly conserved epitopes for HIV-2 detection instead of recombinant gp36 antigen. Despite this some HIV-2 sera may show both the bands with **RAPINDO™ HIV Screen**.
(7) As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
(8) **RAPINDO™ HIV Screen** should only be used as a screening test and its results should be confirmed by other supplemental methods before taking clinical decisions.

**WARRANTY**

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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(11) Data on file: PT Tulip Diagnostics Indonesia.


**SYMBOL KEYS**

| | | | |
|---|---|---|---|
| Temperature Limitation | Consult Instructions for use | Date of Manufacture | Do not reuse |
| Manufacturer | IVD — *In vitro* Diagnostic Medical Device | This side up | BUF — Sample Running Buffer |
| Use by | REF — Catalogue Number | DEVICE — Device | Do not use if package is damaged |
| Contains sufficient for <n> tests | LOT — Batch Number / Lot Number | PIPETTE — Disposable Plastic Sample Applicator | |
| Professional Use only | Xn — Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions. | | |


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**PT TULIP DIAGNOSTICS INDONESIA**
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0625/VER-02